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- 1.) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12, drawn to a tissue adhesive, classified in class 514, subclass 21.
  - II. Claims 13-25, drawn to a bone adhesive, classified in class 514, subclass 2.
- 2.) III. Claims 26-28, drawn to a system for sealing tissues, classified in class 435, subclass 810.
- 3.) IV. Claims 29-36, drawn to a process for producing tissue adhesive, classified in class 530, subclass 345.
- 4.) V. Claims 37-39, drawn to a method for sealing vigorously, classified in class 514, subclass 21+.
- 5.) Inventions I and III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in another and materially different process of use such as the system for sealing tissues of group III and the process of sealing tissues vigorously, or in a pharmaceutical composition.
- 6.) Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

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product as claimed can be produced in any of the well known tissue welding, or fusion or hybrid techniques.

7.) Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together, and have different modes of operation, different functions different effects, and act at different sites in the body.

8.) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9.) Because the inventions are distinct for the reasons given above and the search for each group is different, restriction for examination purposes as indicated is proper.

10.) Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11.) During a telephone conversation with Mr. Louis Cullman on September 9, 1999 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims

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12-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

12.) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13.) Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bass et al. ('362).

The Bass reference teaches tissue bonding and sealing compositions and methods of use. The reference teaches that the components of the adhesive includes proteins which are globular proteins and fibrous proteins which include collagen and albumin. See column 4 lines 11-68 and column 5. The sealant or adhesive also includes crosslinking moieties. The components can be modified. The compositions are activated through the application of energy and/or photons. The reference teaches sound energy in the ultrasonic<sup>frequency</sup> see column 5 lines 65-66.

The instant invention is drawn to a tissue adhesive which comprises a mixture of ultrasonically treated fibrous protein, ultrasonically treated globular protein and a cross linking agent.

The difference in the prior art and the instant invention if there is one, is the specific components and the ratio of ingredient content.

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use ultrasonic energy on the components and to use a crosslinking agent and a fibrous protein and a globular protein as taught by the prior art in view of the prior art disclosures. One would expect the instant invention composition tissue adhesives or sealants in view of the prior art disclosures in the absence of a showing of unexpected results.

14.) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport, whose telephone number is (703) 308-4002.

The examiner can normally be reached on Tuesday-Friday from 8:30 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Christian Low, can be reached on (703)-308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A. Davenport:jmr

April 10, 2000

*Avis M. Davenport*  
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